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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/291,656	03/03/1999	MARC PETERS-GOLDEN	UM-03662	2349

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
03/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/291,656	PETERS-GOLDEN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25,27 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25, 27, and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 1, 2007 has been entered.

Claims 22-25, 27, and 38 are currently pending and under examination.

Benefit of priority is to December 3, 1996.

The Request to Withdrawal Finality of the Office Action mailed September 14, 2007 is denied. Applicants urge that the finality was premature because Applicants amended their claims in response to a request by the Board to make definite their intended claim limitations to Claims 28-37. Upon review of the Decision, it is noted that the Board did not suggest claim language or invite Applicants to enter new matter into the application. Therefore, the finality was necessitated by amendments filed by Applicants.

The Board Decision mailed May 30, 2007 has been reviewed. The Board upheld and added additional reasoning as to why the rejection of Claims 22-25 and 27 as being obvious under 35 U.S.C. 103(a) as being unpatentable over Gosselin et al. (USP 5,789,441; priority to February 15, 1996) is maintained.

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Withdrawal of Rejections:

The Board initiated Rejection under the provisions of 37 C.F.R. § 41.50(b), we [the Board] enter the following new ground of rejection: Claims 28-37 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite, is withdrawn in view of the cancellation of these claims.

Claims 28-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of the cancellation of these claims.

New Rejections:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Gosselin et al. (USP 5,789,441; priority to February 15, 1996).

Gosselin et al. teach leukotriene LTB_4 in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example; Claims 22, 23, and 27). The term "LTB_4" includes leukotrienes C_4, D_4, and E_4 (col. 6, line 52; Claims 25, 27).

The Board stated at pages 7 and 8 of their Decision:

Appellants also argue that the '059 Application does not teach "an aerosol" (Br. 7, 10) and that "[b]ecause 'an aerosol' is not functional

language the Examiner MUST give this claim element full patentable weight" *(id.* at 8). In particular, Appellants argue that "an aerosol is a composition of matter within its own right" (Reply Br. 3).

While we agree with Appellants that claim 22's "wherein" clause limits the claim to a solution in the form of an aerosol, we do not agree that that limitation distinguishes the claimed solution from that of Gosselin. Appellants define an "aerosol" as a solution in one of two forms: "a gaseous suspension of fine solid or liquid particles" or a "substance... packaged under pressure with a gaseous propellant for release as a spray of fine particles" (Reply Br. 2).

Gosselin does not disclose a solution in the form of a gaseous suspension or under pressure with a gaseous propellant. However, a solution is not changed by the composition of the gas overlying it or the pressure of that gas. **A solution comprising a leukotriene, an antibiotic, and a sterile liquid vehicle is the same solution regardless of whether the solution is in an open container (i.e., under air at atmospheric pressure) or whether it is "packaged under pressure with a gaseous propellant." Thus, claim 22's limitation that the "solution is an aerosol" does not distinguish the claimed solution from the solution disclosed by Gosselin and the '059 Application.**

Maintenance of Rejections:

Claims 22 and 38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gosselin et al. (USP 5,789,441; priority to February 15, 1996).

Gosselin et al. teach leukotriene LTB_4 in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example). The term "LTB_4" includes leukotrienes C_4, D_4, and E_4 (col. 6, line 52).

Gossellin et al. do not expressly teach that to include an antibiotic to a solution comprising a sterile liquid and a leukotriene. However, at col. 5, lines 24-29, Gossellin et al. states that the invention provides for the use of an LTB_4 agent as a therapeutic against Gram + and – infections, or fungal infections alone or in association with other antibacterial or antifungal agents.

Therefore, it would have been obvious to a person having ordinary skill in the art to include an antibiotic in a solution comprising a sterile liquid and a leukotriene (Claim 22, 38),

because Gosselin et al. suggests to use LTB_4 with an antibacterial or antifungal agent against Gram+ and – infections, or fungal infections.

The Board stated at pages 7 and 8 of their Decision:

> Appellants also argue that the '059 Application does not teach "an aerosol" (Br. 7, 10) and that "[b]ecause 'an aerosol' is not functional language the Examiner MUST give this claim element full patentable weight" *(id.* at 8). In particular, Appellants argue that "an aerosol is a composition of matter within its own right" (Reply Br. 3).
>
> While we agree with Appellants that claim 22's "wherein" clause limits the claim to a solution in the form of an aerosol, we do not agree that that limitation distinguishes the claimed solution from that of Gosselin. Appellants define an "aerosol" as a solution in one of two forms: "a gaseous suspension of fine solid or liquid particles" or a "substance... packaged under pressure with a gaseous propellant for release as a spray of fine particles" (Reply Br. 2).
>
> Gosselin does not disclose a solution in the form of a gaseous suspension or under pressure with a gaseous propellant. However, a solution is not changed by the composition of the gas overlying it or the pressure of that gas. A solution comprising a leukotriene, an antibiotic, and a sterile liquid vehicle is the same solution regardless of whether the solution is in an open container (i.e., under air at atmospheric pressure) or whether it is "packaged under pressure with a gaseous propellant." Thus, claim 22's limitation that the "solution is an aerosol" does not distinguish the claimed solution from the solution disclosed by Gosselin and the '059 Application.
>
> We affirm the rejection of claim 22. Claims 23-25 and 27 were not separately argued and fall with claim 22. 37 C.F.R. § 41.37(c)(1)(vii). Since our reasoning differs from that of the Examiner, however, we designate our affirmance as a new ground of rejection under 37 C.F.R. § 41.50(b) in order to give Appellants a fair opportunity to respond.

In the paper filed November 1, 2007, at page 3-4, Applicants urge that the Examiner must give patentable weight to the term "aerosol". As noted by the Board, this term does not distinguish over a solution in an open container. Therefore, these rejections are maintained.

No Claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656